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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,678	05/15/1998	VERNON E. ALVAREZ	1101-220	8606

20583 7590 04/08/2003

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NEW YORK, NY 100362711

EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/08/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/079,678

Applicant(s)

ALVAREZ ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 75 and 109-155 is/are pending in the application.
- 4a) Of the above claim(s) 111-116, 129-134 and 143-154 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 75 and 155 is/are allowed.
- 6) ☒ Claim(s) 109, 110, 117-128 and 135-142 is/are rejected.
- 7) ☒ Claim(s) 75 and 142 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This office action is in response to Paper No: 30, received 3/14/03, in which applicant elected SEQ ID NO: 178 and SEQ ID NO: 51, with traverse.

Applicant's election with traverse of SEQ ID NO: 178 from Group I and SEQ ID NO: 51 from Group II in Paper No. 30 is acknowledged. The traversal is on the grounds that to search and examine all the peptides, or all the peptides that bind to a given receptor, would not be an undue burden on the examiner in view of M.P.E.P. 803. Alternatively, applicant requests that various groups be drawn together and examined. This is not found persuasive because the search for each peptide is different and requires extensive database, literature, class and subclass searches. A search of all the peptides, or all the peptides that bind to a given receptor, would constitute an undue burden on the examiner. Further, a search of each group is different and requires extensive database, literature, class and subclass searches. The search of all the groups and species, which include a multitude of individual sequences, would constitute an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 111-116, 129-134, and 143-154 are withdrawn from consideration as being drawn to a non-elected species.

Claims 75, 109-110, 117-128, 135-142, and 155 will be examined in this office action.

### ***Claim Objections***

Claim 75 recites "...a a...", appropriate correction is requested.

Claim 142 depends upon itself, appropriate correction is requested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 109 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 109 recites “...an active agent...”. This is vague and indefinite.

Claim 109 recites “an active agent being of value in the treatment of mammalian disease...”. The disclosure fails to set forth the metes and bounds of an “active agent”. While the specification discloses delivery of “macromolecules, peptides, proteins” and “products of the biotechnology industry, etc. at page 6 (lines 24-25), it is not clear what agents are encompassed within the definition of a peptide, a protein, a macromolecule, or a product of the biotechnology industry and what is encompassed within “etc.”. Absent such disclosure, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Claim 109 recites “an amino acid sequence selected from SEQ ID NOS: 1-55 or a binding portion thereof”. The phrase “or a binding portion thereof” renders the claim indefinite. The specification fails to disclose the metes and bounds of such a binding portion and fails to teach what the binding portion of the protein binds to. If applicant intends the “binding portion”

to be the portion which binds to one of the specifically-recited receptors of claim 109, then the claims should be amended to so indicate.

Claims 110, and 117-126 are included in this rejection for depending upon rejected claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 109, 110, 127, 128, 141 and 142 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a composition comprising a purified protein which specifically binds a gastro-intestinal tract receptor, SEQ ID NO: 178, the protein comprising an amino acid sequence, SEQ ID NO: 51 or a binding portion thereof, wherein the binding portion is claimed (a) without any clear structural limitations and (b) without any functional limitations.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, “requires a precise definition, such as by structure, formula [or] chemical name’, of the claimed subject matter sufficient to distinguish it from other materials” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ 1601, 1606 (Fed.

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Cir. 1993) (background material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claims molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, no mention is made of “a binding portion thereof” in relation to SEQ ID NO:51. The sequence of SEQ ID NO: 51 does not describe the structure of the binding portion nor can the binding portion be predicted based upon the disclosure since binding characteristics have not been described.

Claims 135-140 are included in this rejection for depending upon a rejected claim.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dantzig (USPN 5,620,855) teaches a mammalian influx peptide transporter in which SEQ ID NO:1 has 100% query match with applicant's SEQ ID NO:178, see column 11, SEQ ID NO: 1. However, as reads on SEQ ID NO: 51, it is declared free of the art.

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Claims 75 and 155 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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4/4/03  
RT

*Brenda Brumback*  
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